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Hoffmann & Baron LLP
6900 Jericho Turnpike
Syosset, NY 11791

EXAMINER	
LANG, AMY T	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/691,849
Filing Date: October 22, 2003
Appellant(s): CHOBOTOV ET AL.

John S. Sopko
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12/09/2008 appealing from the Office action mailed 06/26/2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

2006/0263301	VERNON ET AL.	11-2006
2006/0224227	CHOBOTOV	10-2006
2005/0090901	STUDER	4-2005
5,059,211	STACK ET AL.	10-1991

2005/0052946	ARGENTINE	3-2005
60465376	VERNON	4-2003

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **Claims 51, 52, and 63** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 51, 52, and 63 recite wherein the polyethylene glycol diacrylate (PEGDA) consists essentially of polyethylene glycol having a molecular weight between 700 and 800. It is the examiner's position that the instant specification does not support the limitation of consisting essentially of. Although paragraph [0061] of the specification teaches the PEGDA may comprise a molecular weight between 700 and 800, the specification does not teach consisting essentially of the specified molecular weight.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. **Claims 31, 33, 35, 36, 44-46, 50-54** are rejected under 35 U.S.C. 103(a) as being unpatentable over Vernon et al. (US 2006/0263301 A1) in view of Chobotov (US 2006/0224227 A1) and Studer (US 2005/0090901 A1).

With regard to **claims 31, 33, 35, 45, 46, 51, 53, and 54**, Vernon et al. (hereinafter Vernon) discloses a gelling material that is used to occlude abnormal vasculature in a patient's body ([0002]). The curable material comprises polyethylene glycol diacrylate (PEGDA), pentaerythritol-tetrakis(3-mercaptopropionate), and a buffer, where pentaerythritol-tetrakis(3-mercaptopropionate) clearly overlaps the instantly claimed pentaerythritol tetra 3(mercaptopropionate) ([0104]; [0086], [0088]). Vernon further teaches wherein the gelling material is introduced in the abnormal vasculature via a catheter syringe, which clearly overlaps the instantly claimed delivery device

([0091]; [0102]). This catheter syringe is clearly capable of accessing perigraft space between an endovascular graft and a lumen wall. Vernon further teaches wherein the catheter comprises a balloon that occludes the vasculature to reduce blood flow through the abnormal vasculature ([0095]).

Vernon teaches wherein the gelling material is utilized to occlude an abnormal vasculature, specifically any known embolization technique ([0107]). An aneurysm is a common abnormal vasculature that is occluded with a stent graft, as is well known in the art. However, Vernon does not specifically disclose a stent-graft that comprises an inflatable graft.

Chobotov discloses a stent-graft utilized to treat an aneurysm ([0002]). As shown in Figures 1 and 10, the graft comprises proximal and distal cuffs (64 and 65) and an inflatable channel (93) ([0040]; [0047]). Since Chobotov discloses a well-known stent-graft that treats an abnormal vasculature, it would have been obvious at the time of the invention for Vernon to utilize the stent-graft of Chobotov.

Vernon in view of Chobotov would therefore produce a system for deploying a gelling material into the abnormal vasculature, an aneurysm, which is also occluded with the stent-graft of Chobotov. Therefore, the gelling material would be delivered in the perigraft space between the stent-graft and a vessel lumen wall.

The PEGDA of Vernon comprises a molecular weight of 570 ([0086]). However, it is well known in the art to utilize PEGDA with higher molecular weights, absent evidence to the contrary. Studer discloses a PEGDA with a molecular weight of 700 to occlude an intervetebral space ([0042]). Therefore, it would have been obvious to one

of ordinary skill in the art for Vernon to utilize PEGDA with a higher molecular weight, specifically 700.

With regard to **claim 36**, Vernon further discloses adding a radiopaque agent to the gelling material ([0087]).

With regard to **claim 44**, since the gelling material is disclosed as curing once in the patient's body to form a gelled composition, the material intrinsically comprises a first viscosity upon delivery to the perigraft space ([0104]). The material then is solid once the material has cured into the gelled composition.

With regard to **claim 50**, the polyethylene glcycol is utilized in Example 3 of Vernon at 52 wt% (997mg/1894mg), which clearly overlaps the instant claim ([0116]).

With regard to **claim 52**, the pentaerythritol-tetrakis(3-mercaptopriopionate) is in a proportion 0.43 times the weight percent of the polyethylene glycol diacrylate in Example 3 of Vernon.

6. **Claim 32** is rejected under 35 U.S.C. 103(a) as being unpatentable over Vernon et al. (US 2006/0263301 A1) in view of Chobotov (US 2006/0224227 A1) and Studer (US 2005/0090901 A1) as applied to claim 31 above, and further in view of Stack et al. (US 5,059,211).

Vernon in view of Chobotov and Studer disclose a system for deploying a gelling material to an abnormal vasculature. An occlusion balloon, delivered on a catheter, is utilized to reduce blood flow through the abnormal vasculature. Although Vernon in view of Chobotov and Studer does not specifically disclose the catheter as comprising a guidewire, it is well known in the art for guidewires to aid in the delivery of a catheter

through a patient's vasculature. Stack et al. (hereinafter Stack) teaches a catheter guided with the aid of guidewire (column 3, lines 36-37). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention for the catheter of Vernon in view of Chobotov and Studer to comprise a guidewire so that the occlusion balloon is positioned adjacent the distal end of the guidewire.

7. **Claims 37, 38, 40-43, 48, 49, and 56-65** are rejected under 35 U.S.C. 103(a) as being unpatentable over Vernon et al. (US 2006/0263301 A1) in view of Chobotov (US 2006/0224227 A1) and Studer (US 2005/0090901 A1) as applied to claim 31 above, and further in view of Argentine (US 2005/0052946 A1).

With regard to **claims 37, 38, 41, 48, and 49** Vernon in view of Chobotov and Studer disclose a system for deploying a gelling material to an abnormal vasculature. The gelling material comprises a buffer such as saline utilized in an amount of 25 wt% (473mg/1894mg) of the total gelling composition ([0088]; Example 3, [0116] of Vernon). However, Vernon in view of Chobotov and Studer does not specifically disclose the buffer as glycylglycine.

Argentine teaches that glycylglycine buffer is a common alternative to saline buffer ([0084]). Additionally, Argentine discloses a curable material that comprises glycylglycine buffer from 22-27 wt% ([0076]; [0077]). Since Argentine teaches that it is known in the art to utilize the buffer glycylglycine in a curable material used in a patient's vessel ([0076]), it would have been obvious at the time of the invention for Vernon in view of Chobotov and Studer to also utilize glycylglycine buffer in the amount disclosed by both Vernon and Argentine.

With regard to **claim 40**, the polyethylene glcycol is utilized in Example 3 of Vernon at 52 wt% (997mg/1894mg), which clearly overlaps the instant claim ([0116]).

With regard to **claims 42 and 56-63**, the pentaerythritol-tetrakis(3-mercaptopriopionate) is in a proportion 0.43 times the weight percent of the polyethylene glycol diacrylate in Example 3 of Vernon.

With regard to **claims 43 and 64**, Vernon further discloses bases and surfactants in the gelling composition that clearly overlap the instantly claimed inert biocompatible materials.

With regard to **claim 65**, since the gelling material is disclosed as curing once in the patient's body to form a gelled composition, the material intrinsically comprises a first viscosity upon delivery to the perigraft space ([0104]). The material then is solid once the material has cured into the gelled composition.

(10) Response to Argument

Appellant's arguments, with respect to the 112 1st 35 USC rejection have been fully considered and are persuasive. Appellant argues that the specification provides support for the claimed language "consists essentially of polyethylene glycol diacrylate having a molecular weight between 700 and 800." This argument has been found persuasive and the rejection is withdrawn.

Appellant's arguments with respect to the molecular weight of polyethylene glycol diacrylate have been fully considered but they are not persuasive.

Specifically, Appellant argues (A) that the Final Rejection provides no rational or degree of predictability why one of ordinary skill in the art would modify the molecular weight of Vernon with the teachings of Studer.

With respect to argument (A), Vernon discloses the same curable embolic material comprising polyethylene glycol diacrylate (PEGDA), pentaerythritol tetra 3(mercaptopropionate), and a buffer. However, Vernon does not specifically disclose the molecular weight of the PEGDA as between 700 and 800. It is well known in the art though, to use PEGDA with various molecular weights to achieve the desired properties of the composition. Studer provides evidence of such by disclosing the same PEGDA material, with a molecular weight of 700, which is used to occlude an intervetebral space. The PEGDA copolymer is incorporated into an empty pouch in an intervetebral disk and then cured to substantially fill the pouch. Therefore, Studer teaches that PEGDA material with a molecular weight of 700 is well known and advantageous since it is a curable flowable material that can be easily cured by photo-polymerization through a light guide ([0025]; [0036]). Since Studer teaches an advantageous PEGDA, used to occlude an interior space, with a molecular weight of 700 as well known in the art, it would have been obvious at the time of the invention for Vernon to also use PEGDA with a molecular weight of 700 to occlude the interior space. Furthermore, since PEGDA with a molecular weight of 700 is so well known in the art and Studer provides one example, a rational for the combination of these references has been provided. Additionally, since Studer teaches the same material in an occluding manner

that is similar to the occluding manner of Vernon, at least some degree of predictability has been provided.

Specifically, Appellant argues (B) that Vernon does not qualify as prior art to meet the claim limitations since the provisional application fails to disclose a particular molecular weight of the disclosed PEGDA.

With respect to argument (B), although it may or may not be true that the provisional application of Vernon does not specifically teach a molecular weight of 700 for the PEGDA, the provisional in view of Studer still overlaps the instant claims. With the provisional being silent as to the molecular weight and Studer providing an advantageous PEGDA with a molecular weight of 700 as is well known in the art, it still would be obvious to combine the provisional application of Vernon with the teachings of Studer. If the provisional is silent regarding a preferred molecular weight, a stronger combination is then provided since the teachings of Studer are not changing the molecular weight but instead are allowing one to employ the teachings for the disclosed advantages.

Specifically, Appellant argues (C) that Vernon does not overlap dependent claim 52 since the provisional application of Vernon does not provide the same example, used in the Final Rejection, which specifies the amount of pentaerythritol to the PEGDA.

With respect to argument (C), although it may or may not be true that the provisional application of Vernon does not teach the same ratio of pentaerythritol to

PEGDA as the PGPUB, the provisional application does teach using the two compounds in various proportions with respect to each other (see page 9, 3rd paragraph). Therefore, it would have been obvious at the time of the invention to utilize differing amounts of the two compounds to achieve a desired result. Additionally, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, USPQ 233 (CCPA 1955). In the instant case, the provisional application teaches using different amounts of the compounds which clearly discloses the general conditions of the claim.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Amy T Lang/
Examiner, Art Unit 3731

Conferees:
/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731

/Tom Hughes/
TQAS, TC3700